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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,913

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

10/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,913	Applicant(s) UDAGAWA ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/19/06, 7/7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 1-15 are currently pending. Claims 1-8 and 10-15 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claim 9 is withdrawn from consideration.

Election/Restrictions

In the response of Jul. 23, 2009, applicants elected the following species:

Resolvent: 2-octyl-1-dodecanol (aka, EUTANOL)

Alkyl(meth)acrylate: dodecyl methacrylate (aka, lauryl methacrylate or 2-methyl-2-propenoic acid dodecyl ester)

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In the response dated Jul. 23, 2009, applicants have stated that claims 1-10 read on the elected species 2-octyl-1-dodecanol. However, 2-octyl-1-dodecanol does not contain a double bond in its carbon chain. Thus, claim 9 cannot read upon the elected species and is withdrawn from consideration. Further, it is noted that claim 10 recites octyl dodecanol, which can be construed as a distinct chemical species from 2-octyl-1-dodecanol. A call was made on Oct. 27, 2009 to Susan Mack to clarify the species election. The examiner stated that claim 10 did not appear to read on the elected species and would be withdrawn. However, upon further consideration, the name "octyl dodecanol" is chemically ambiguous, and could *encompass* 2-

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octyl-1-dodecanol. Thus, claim 10 will be construed as reciting any octyl dodecanol, regardless of the placement of the alkyl chains, thus encompassing applicants' elected species. Claims 1-8 and 10-15 will be examined further on the merits of the claims.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

Specification (Title)

The title of the invention is not adequately descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Specifically, the title should include, at a minimum, a reference to tulobuterol, and the other elements of the claimed patch that applicants are relying upon to distinguish over the prior art.

Specification

The specification is objected to because the claim for domestic priority to PCT/JP04/17305 has not properly been made.

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/JP04/17305, filed 11/19/2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant

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application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-8 and 10-15 are indefinite in the recitation of various "parts" without properly defining standard to which said "parts" are relative. For example, are the recited "parts" by weight, relative to the base material (i.e. backing or support), the adhesive matrix, or the total weight of the patch? One of ordinary skill in the art could reasonably construe the recited "parts" to be relative to either of these or other possibilities. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in the specification, the metes and bounds of claims 1-8 and 10-15, are indefinite.

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Priority

Acknowledgment is made of applicants' claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Japanese application was filed with the USPTO on 5/19/06. In the case that an intervening reference is applied in a rejection, applicants will be entitled to the foreign priority date for the purpose of overcoming the date of the reference, provided that a certified English language translation is supplied and it is determined that the corresponding foreign application supports the claims in the manner required by 35 U.S.C. 112, first paragraph. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over BRACHT (WO 00/64418; Published Nov. 2, 2000) in view of NAKANO (U.S. 6,117,447; Issued Sep. 12, 2000; 1st Ref. on IDS dated 5/19/06) as evidenced by U.S. 6,689,379.

Since the WO document to Bracht is in German, U.S. 6,689,379, the national stage filing resulting from the international application, is relied upon herein as an English language equivalent. Column and line numbers refer to the '379 Patent.

1. Bracht discloses transdermal therapeutic patch systems that comprise pressure-sensitive adhesives and tulobuterol in an amount of 5% (title; abstract; col. 6, line 4; col. 7, lines 61-65; claims 1 and 2). Bracht teaches the use of 2-octyl dodecanol (i.e. elected species) in the transdermal preparations as a permeation enhancer in quantities from 10-80 % relative to the adhesive matrix (col. 6, lines 15-17; claim 10). Bracht teaches that polymers suitable for the formation of the pressure sensitive adhesive layer include polyacrylates constructed from both acrylic acid and methacrylic acid units or ester derivatives thereof (abstract; col. 1, lines 10-20;

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col. 2, line 59 to col. 3, line 3). Bracht does not teach the instantly elected species of alkyl(meth)acrylate.

2. Nakano discloses percutaneous preparations comprising a support and an acrylic adhesive plaster layer laminated thereon which comprises tulobuterol in at least 5%. Nakano teaches that the acrylic adhesive comprises a copolymer comprising an alkyl(meth)acrylate having an alkyl group of up to 12 carbon atoms, the monomer in a proportion of not less than 50% (abstract; col. 2, lines 11-30). Nakano teaches the use of copolymers comprising 2-ethylhexyl(meth)acrylate and/or dodecyl(meth)acrylate (i.e. elected species) as a monomer in preferably not less than 60%, particularly in amounts of 60-98% (i.e. greater than 70%) (col. 3, lines 50-53; particularly col. 4, lines 6-11).

3. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use dodecyl(meth)acrylate as an esterified methacrylate monomer of Bracht's invention in amounts of greater than 70% as taught by Nakano. One would have been motivated to do so since Nakano teaches this very type of acrylate copolymer is a suitable choice for tulobuterol transdermal preparations. Further, both Bracht and Nakano are concerned with similar problems in the art, namely, the production of stable, transdermal delivery preparations for tulobuterol. Claims 1-8 and 10-15 are obvious over Bracht and Nakano.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In*

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re Bode 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

Claims 1-8 and 10-15 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/

Primary Examiner, Art Unit 1643